

U.S.S.N. 10/083,413

Filed: February 27, 2002

## AMENDMENT AND RESPONSE TO OFFICE ACTION

## Amendment

## In the Claims

1. (currently amended) A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective bioactive amount of at least one herbal active agent or homeopathic active agent, wherein the herbal active agent is selected from the group consisting of a bioactive herb extract herbs, herbal extracts, a tincture tinctures, an essential oil oils, and mixtures thereof; or an agent selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and

(b) a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa; and

(c) Carnallite or a salt of Carnallite.

2. (currently amended) A The solid composition according to of claim 1 wherein said the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes.

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3. (currently amended) A The solid composition according to of claim 1 where said the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

4. (currently amended) The composition according to of claim 1 wherein the herbal active agent is at least one selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, and an antiparasite agent agents, and combinations thereof.

5. (canceled)

6. (currently amended) A The composition according to of claim 1 wherein the herbal active agent or homeopathic agent is at least one selected from the group consisting of Getu Kela, Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, Elder, menthol, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycrrhiza, Angelica, Kramerica, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof.

7. (currently amended) The composition of claim 1, wherein the herbal active agent is at least one an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil,

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pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

8. (currently amended) The composition of claim 7, wherein the herbal active agent is at least one an essential oil selected from the group consisting of cinnamon oil, tea-tree oil, and citronella oil, and combinations thereof.

9. (currently amended) A The composition according to of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. (currently amended) A The composition according to of claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene, a-pinene, b-pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. (currently amended) A The composition according to of claim 9, wherein said the monoterpenes monoterpene with three unsaturations is at least one a citrus oil selected from the group consisting of lemon oil, pomelo oil, and citron oil, and combinations thereof.

12. (currently amended) A The composition of claim 6 1, further comprising a salt selected from the group consisting of MgBr<sub>2</sub>, NaCl, KCl and mixtures thereof.

13. (canceled)

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14. (currently amended) A The composition according to of claim 1 wherein said further comprising Carnallite or a salt of Carnallite is present in an amount of about 5-50% wt/wt based on the amount of the at least one herbal active agent or homeopathic active agent.

15. (currently amended) The composition of claim 1, further comprising a non-herbal active agent selected from the group consisting of anesthetic agent, analgesics, steroid and non-steroidal anti-inflammatory agents, antihistamine or antiallergies, steroids, antimicrobial drugs, vitamins, enzymes, anti-allergic drugs, antipyretics, antimalarial, antiulcer drugs, peptides, DNA plasmid plasmids, antisense-based therapeutic agents, and combinations thereof.

16. (currently amended) The composition of claim 15, wherein the anesthetic agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chloroprocaine, tetracaine, bupivacaine, and etidocaine.

17. (previously presented) The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

18. (Canceled) The composition of claim 4, wherein said Carnallite or a salt of Carnallite improves the activity of the herbal active agents.

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19. (currently amended) The composition of claim [4] 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. (currently amended) The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 and 1:1.

21. (previously presented) The composition of claim 15 comprising a citron oil and Carnallite salt at a weight ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivacaine.

22. (currently amended) The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.

23. (currently amended) The composition of claim 22 wherein said the polyhydric polymer comprises at least one member is selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, acrylic acid copolymers, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof.

24. (currently amended) ~~A solid, self bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:~~

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(a) — ~~a therapeutically effective amount of at least one herbal active agent or homeopathic active agent wherein the herbal active agent is selected from the group consisting of a bioactive herb extract, a tincture, an essential oil, and mixtures thereof; and~~

(b) — ~~a pharmaceutically acceptable solid bioadhesive carrier in an amount from about 40 to 99 percent by weight of the whole composition, wherein the solid bioadhesive carrier is selected from the group consisting of a natural, semisynthetic or synthetic polyhydric polymer, a polycarboxylic acid polymer, and mixtures thereof; and~~

(c) — ~~Carnallite or a salt of Carnallite;~~

~~wherein the solid bioadhesive composition is in the form of a tablet wherein said the composition additional contains one or more members~~ The composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and lubricants and mixtures thereof.

25. (currently amended) The composition according to of claim 24 wherein said the enhancers are selected from the group consisting of bile acids and limonene.

26. (currently amended) The A composition according to of claim 22 wherein said the solid bioadhesive carrier is selected from polyacrylic acid polymers lightly crosslinked with a polymer selected from the group consisting of polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose, and mixtures thereof.

Claims 27-37. (canceled)

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38. (new) The composition of claim 1, wherein the composition has a surface area ranging from about 0.4 to about 3 cm<sup>2</sup>.

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